



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,169	01/02/2001	Cy A. Stein	55669-A-PCT-US/JPW/GJC	9695
7590	02/08/2005			
EXAMINER				
EPPS FORD, JANET L				
ART UNIT		PAPER NUMBER		
1635				

DATE MAILED: 02/08/2005

John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/753,169

Applicant(s)

STEIN ET AL

Examiner

Janet L. Epps-Ford, Ph.D.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5 and 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 is/are allowed.
- 6) ☐ Claim(s) 5 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5-10-04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-19-2004 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 5 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (Written Description).

Claim 5 is drawn to an antisense oligonucleotide comprising 10 or more contiguous bases of the nucleotide sequence set forth in any one of SEQ ID NO: 1 and 3-13, wherein the oligonucleotide is conjugate to a peptide and wherein the oligonucleotide is complementary to a bcl-xL-encoding mRNA and inhibits translation thereof. The instant claims are drawn to antisense oligonucleotides of undefined length comprising a minimal of 10 contiguous bases of any one of SEQ ID NO: 1, and 3-13.

Art Unit: 1635

Although Applicants have required that the claimed antisense comprise 10 or more contiguous bases of SEQ ID NO: 1 and 3-13, and that the antisense oligonucleotide comprise a sequence that is complementary to a bcl-xL encoding mRNA. The fact remains that the instant claims read on antisense oligonucleotides of any length, targeting any particular form of bcl-xL encoding mRNA, which encompasses all forms isolated from any species expressing this mRNA, including all allelic, and splice variants of bcl-xL mRNA, mutated forms of bcl-xL mRNA and analogs thereof. In order to identify the complete structure of the antisense compounds of the present invention, the skilled artisan would have to know the nucleotide structures of all bcl-xL mRNA sequences such that remaining sequence, beyond that described as comprising 10 or more bases of SEQ ID NO: 1, and 3-13, can be designed such that the sequence is complementary to all variants of bcl-xL mRNA target sequences. Moreover, once the antisense compound (of undefined length) is designed, the skilled artisan would have to test the antisense compound for its ability to inhibit the translation of bcl-xL mRNA, since Applicants have not provided a clear correlation between the nucleotide base composition of the antisense compound and its ability to inhibit the translation of bcl-xL mRNA translation.

One of ordinary skill in the art would not be able to predict the structures of all nucleotide sequences of all the antisense oligonucleotide compounds encompassed by the instant claims, because they comprise a broad number of nucleotide sequences, and there is no common structure shared among the species that is related to any particular common function, i.e. to inhibit translation of bcl-xL mRNA, or reduce the expression of bcl-xL, without the need for further experimentation.

Art Unit: 1635

4. See MPEP § 2163, which states “[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.”

Double Patenting

5. Claims 5, and 43 remain provisionally rejected under the judicially created doctrine of double patenting over claims 9, 36-50, 53-54, 58, and 61-62 of copending Application No. 09/832,648 in view of Manoharan et al. Sanghvi et al., Matteucci et al. and Arnold et al. for the reasons of record set forth in the prior Office Action mailed 6-18-03; and remain provisionally rejected over claims 37-43, 51-53, 58, and 61-62 of copending Application No. 10/160,344, for the reasons set forth in the Office Action mailed 5-19-04.

6. Applicant's arguments filed 9-22-04 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the claims of the copending applications referred to by the examiner have not been allowed, and that if the Examiner's remaining rejections are obviated by the amendments and arguments made hereinabove then the pending claims should be allowed in the absence of the allowance of the applications over which the double patenting rejections have been made. However, in the instant case, the rejections over claims 5 and 43 have not been obviated by Applicant's amendments, therefore the provisional double patenting rejections of the instant claims over Applications 09/832,648 and 10/160,344 are maintained. It is also noted that the instant application and copending applications 09/832,648 and 10/160,344, share at least one common inventor, and at least one common assignee.

Art Unit: 1635

Conclusion

7. Claim 9 is allowable over the prior art, and the copending applications since the instant application has an earlier filing date than copending applications 09/832,648 and 10/160,344.

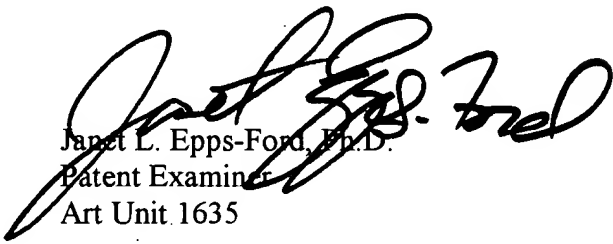
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


Janet L. Epps-Ford, Ph.D.
Patent Examiner
Art Unit 1635

JLE